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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,679	09/12/2005	Charles Henry Horn	05-038	2351

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EXAMINER	
HENKEL, DANIELLE B	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,679	HORN, CHARLES HENRY	
	Examiner	Art Unit	
	DANIELLE HENKEL	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-62 and 64-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-62 and 64-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/13/2010 has been entered.

2. Claims 56-62 and 64-78 are pending and have been fully considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 60-62, 64-70, 72-74, and 76 rejected under 35 U.S.C. 102(b) as being anticipated by BOCQUET (US 4583971).

a. With respect to claim 60, BOCQUET discloses a unitary, disposable, and portable mixing and delivery apparatus comprising one flexible container, 12 (proliferation chamber) having a liquid solution (growth medium); at least one drug vial, 36 containing a drug (inoculum) with the drug vial exterior to the flexible chamber; and a rubber stopper, 40 separating the container and vial having a

capsule with hollow needle in a tube, 22 (coupling means) coupling to the interior of the flexible container and drug vial and a communicating means openable to connect the interiors to each other without compromising the closed, sterile chambers to allow mixing (Column 3, line 11- Column 4, line 60; Figures 1 and 2) and wherein the drug (inoculum) is provided in a form that is stable and viable longer than a normal mixed drug in a closed container (Column 1, lines 33-42). The device of BOCQUET is capable of being used as an anaerobic microorganism proliferation device as it is a completely closed and sterile system and therefore is not gas permeable (anaerobic) (Column 2, lines 14-18 and Column 5, lines 51-62). While BOCQUET does not explicitly disclose the device being used for culture and proliferation it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations *Ex parte Masham* 2 USPQ2d 1647 1987).

b. With respect to claim 61, BOCQUET discloses the device is arranged so that the drug (inoculum) and diluent (growth medium) are stored and transported separately until mixing (proliferation) and the mixture is dispensed from the device (Column 2, lines 14-17; Column 3, lines 11-31 and Column 4, lines 15-17).

c. With respect to claim 62, BOCQUET discloses the vial with stopper (separating means) and flexible container (proliferation chamber) are sterilized prior to use (Column 5, lines 51-62).

d. With respect to claim 64, BOCQUET discloses the device is completely closed and sterile (hermetically sealed) (Column 3, lines 11-13 and Column 4, lines 33-34; Figure 1).

e. With respect to claim 65, BOCQUET discloses the flexible container and vial are connected via a capsule with a hollow needle in a tube (passage) (column 4, lines 54-59; Figure 2).

f. With respect to claim 66, BOCQUET discloses a rubber stopper (septum) separating the drug vial and flexible container (chambers) (Column 4, lines 40-44).

g. With respect to claim 67, BOCQUET discloses a needle with a spike tip for piercing the rubber stopper (Column 4, lines 54-59 and Column 5, lines 30-32).

h. With respect to claim 68, BOCQUET discloses the drug (inoculation) container is a standard vial having an opening (mouth) which is connected to the capsule with hollow needle (Column 4, lines 40-44; Figure 2).

i. With respect to claim 69, BOCQUET discloses the rubber stopper (septum) covers the vial opening (column 4, lines 40-44; Figure 2).

j. With respect to claim 70, BOCQUET discloses the needle with spike tip is mounted in the tube (passage) directed at the rubber stopper (septum), and the drug vial is connected to the end of the passage by the capsule (advancement means) so that in use the drug vial is advanced towards the spike tip until it pierces the stopper (Column 5, lines 24-39 and Figure 2).

k. With respect to claim 72, BOCQUET discloses the device is provided with urging means for urging the drug (inoculum) into the container after the stopper is pierced (Column 5, lines 9-39).

l. With respect to claim 73, BOCQUET discloses a pressure difference between the container and vial causes the drug (inoculum) to flow into the container (proliferation chamber) after the stopper has been opened to allow for mixing (proliferation) (Column 5, lines 19-23).

m. With respect to claim 74, BOCQUET discloses the container has a port for connecting to a delivery means (Column 4, lines 15-21).

n. With respect to claim 76, BOCQUET discloses the container is a flexible infusion bag (Column 4, lines 9-11, Figure 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 56-59, 71, 75, and 77-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over BOCQUET (US 4583971).

a. With respect to claim 56, BOCQUET discloses mixing and delivery of a drug (proliferation) including disposing a drug in a drug vial (inoculation chamber), disposing a diluent (medium) for the drug in a flexible container (proliferation chamber) with the drug vial being exterior of the container and a rubber stopper, 40 (openable separating means) separating the container and vial; storing the drug and diluent separately; piercing the stopper to allow the drug to mix with the diluent (opening); allowing the drug and diluent to mix in the container and form a mixed drug product (proliferated culture) and dispensing the mixed drug from the container wherein the piercing step takes place in a completely closed and sterile device (Column 3, line 11- Column 4, line 60; Column 5, lines 26-62; Figures 1 and 2). The method of BOCQUET is capable of being used as an anaerobic microorganism proliferation device as it is a completely closed and sterile system and therefore is not gas permeable (anaerobic) (Column 2, lines 14-18 and Column 5, lines 51-62). While BOCQUET does not explicitly disclose the device being used for culture and proliferation it would have been obvious for one of ordinary skill in the art to use the known sterile, closed device of BOCQUET for any purpose requiring separate storage and subsequent mixing of two substances without contact with the external environment such as anaerobic culturing.

b. With respect to claim 57, BOCQUET discloses the drug (inoculum) is provided in a form that is stable and viable longer than a normal mixed drug in a closed container (Column 1, lines 33-42).

c. With respect to claim 58, BOCQUET discloses the vial with stopper (separating means) and flexible container (proliferation chamber) are sterilized prior to use (Column 5, lines 51-62).

d. With respect to claim 59, BOCQUET discloses performing the method in a laminar flow hood or a sterilized room with portholes (control over conditions) (Column 5, lines 51-62 and Column 2, lines 1-2).

e. With respect to claim 71, BOCQUET discloses applying pressure to the flexible container to pressurize the fluid in the vial to flow back into the chamber, (Column 5, lines 9-39) but does not explicitly disclose the vial being flexible so that it is compressed. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the vial flexible for compression instead of the container, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

f. With respect to claim 75, BOCQUET discloses the flexible container is pressurized to allow for drug flow in the device (Column 5, lines 9-39), but does not explicitly disclose the pressure is due to anaerobic cultivation. However, it would have been obvious to one of ordinary skill to use any known source of pressure to cause the drug to flow from the flexible container. The device of

BOCQUET has a container which is capable of being pressurized by anaerobic cultivation to cause fluid flow.

g. With respect to claim 77, BOCQUET does not explicitly disclose the container is a carboy type container, however, it would have been an obvious matter of design choice to chose any known laboratory container such as a carboy in the practice of the disclosed invention as known laboratory containers would provide the same closed, sterile function of the container of BOCQUET.

h. With respect to claim 78, BOCQUET does not explicitly disclose additional containers connectable to the vials. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the additional containers, since it has been held that mere duplication of the essential working part of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

8. Applicant's arguments with respect to claims 56-62, and 64-78 have been considered but are moot in view of the new ground(s) of rejection over BOCQUET as necessitated by amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is

(571)270-5505. The examiner can normally be reached on Mon-Thur: 11am-8pm, Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on 571-272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DANIELLE HENKEL/
Examiner, Art Unit 1797

/Michael A Marcheschi/
Supervisory Patent Examiner, Art Unit 1797